



Henning Gädeke,
Chair of the EDCTP Association Board and the Global Health EDCTP3

c/o Dr. Michael Makanga, Executive Director of the Global Health EDCTP3 Joint Undertaking

Global Health EDCTP3 Joint Undertaking
56 – 60 Avenue de la Toison d'Or
1060 Brussels
Belgium

Letter of endorsement

Dear Sir/Madam,

On behalf of the management and directors of LT Clinical Research (Pty) Ltd, and in accordance with Council Regulation (EU) No 2085/2021 of 19th November 2021 of 19th November 2021 establishing the joint undertakings under Horizon Europe and specifically Article 9 therein, we hereby apply to become a contributing partner to the Global Health EDCTP3 Joint Undertaking (Global Health EDCTP3 JU).

LT Clinical Research is a regional Contract Research Management Organisation (CRO) based in South Africa, with 14 years of experience offering a comprehensive suite of services to support the development and management of clinical trials in Southern Africa. The company has a proven track record of effectively managing clinical trials from start to finish. This includes protocol development, patient recruitment and retention, site management, and data collection. Our experience ensures that trials are conducted efficiently and in compliance with all relevant regulations.

LT Clinical Research provides crucial support in regulatory affairs, assisting with submissions to ethics committees and regulatory authorities, ensuring that all necessary approvals are secured promptly. A unique strength of LT Clinical Research is its commitment to strengthening the local clinical trial ecosystem. The company offers training and support to clinical trial sites, focusing on Good Clinical Practice (GCP) and Good Clinical Laboratory Practice (GCLP). This capacity building not only enhances the quality of research conducted at these sites but also contributes to the sustainable growth of clinical research in the region.

LT Clinical Research (Pty) Ltd is dedicated to utilising its expertise to support the TESA network in achieving its objectives under Work Packages 3 (WP3) and 5 (WP5).

Our primary focus will be on coordinating efforts to:

1. WP3 - Strengthen Ethical and Regulatory Authority Systems through guiding the Ministries of Health (MOHs) to close the gap in setting up national health research ethics councils (NHRECs).

2. WP5 - Enhance the capacity of entry-and mid-level clinical staff through targeted short-term training courses in Good Clinical Practice (GCP), Good Clinical Laboratory Practice (GCLP), CRA and Clinical Trial Monitoring, and Health Research Ethics, to conduct high-quality human clinical research and trials.

The short-term training programs will prioritise practical application through case studies and role-playing exercises, enabling participants to effectively translate theoretical knowledge into solutions for real-world challenges faced in human clinical research and trial settings.

LT Clinical Research will make the in-kind contributions as detailed in the table below.

Third-party name	Category	Cost (€)	Justification
LT Clinical Research (LTCR)	Meetings & Workshops	24,000.00	To support key initiatives, LTCR can second its Director of Business Development to participate in consortium meetings, a co-facilitator role in the delivery of short-term courses, and projects with no direct claiming for time payment for the duration of the grant.
LTCR	Mentorship and Support	30,000.00	LTCR can provide consortium members/sites with additional and structured brief virtual and online mentorship and support for implementing GCP or GCLP guidelines at their sites for the duration of the grant period. This support is designed to ensure sites operate at the highest standards of quality and compliance.
LTCR	Advocacy & Industry Expert as a guest(s)	10,000.00	The LTCR is capable of coordinating with an expert or two to present an in-person keynote speech to provide support and guidance to the consortium.
LTCR	Business development	50,213.04	As a CRO, LTCR can leverage its business development resources and relationships to source new collaborations that strengthen the consortium and or clinical trial for site(s).
LTCR	Ethics Capacity Support	20,000.00	LTCT can coordinate interactions on behalf of the consortium with members and officials of the SA NHREC
Total		134,213.04	

We confirm the following:

- We will comply with the Horizon Europe Regulation (EU) No 2021/695; Council Regulation (EU) No 2085/2021 establishing the joint undertakings under Horizon Europe; the Model Grant Agreement for Horizon Europe and applicable Global Health EDCTP3 JU rules, including the relevant work programmes and, in particular, the call conditions therein.
- We will keep all information received in the context of our involvement as a contributing partner to the Global Health EDCTP3 JU confidential. This confidentiality obligation applies in particular, but is not limited to, the areas of Global Health EDCTP3 JU call topic preparation and publication, proposal submission and evaluation, and consortium formation. We further understand that this obligation strictly prohibits the release of confidential information to any legal entity save where specifically authorised by Global Health EDCTP3 JU. Internal dissemination of information within our organisation will be done based on the “need-to-know” principle.
- We are confident of our ability to fulfil the above commitments and further confirm our understanding that the Global Health EDCTP3 JU will allocate resources to the above topic based on these commitments.
- The value of our contribution will be based on costs calculated in accordance with Article 6 of the Horizon Europe Model Grant Agreement.
- We accept that additional modalities regarding the provision of our contribution may be defined in subsequent agreements or documents, such as a funding agreement and topic text.

Yours faithfully,

Sibusiso B. Mdlalose
For and on behalf of LT Clinical Research (Pty) Ltd
24 September 2025
